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PATENT SPECIFICATION

(11) 1 489 052

1 489 052

(21) Application No. 35331/76 (22) Filed 25 Aug. 1976

(31) Convention Application No. 2538716

(32) Filed 30 Aug. 1975 in

(33) Federal Republic of Germany (DT)

(44) Complete Specification published 19 Oct. 1977

(51) INT CL² C08J 5/00 C08G 18/10//A61F 7/00

(52) Index at acceptance

C3R 32A 32D6A 32D6J 32D6K 32E1 32G1X 32G1Y 32G2X
32G2Y 32KH 32KK C12 C16 L2CX

A5R 91

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(54) BANDAGES CONTAINING WATER

(71) We, BAYER AKTIENGESSELLSCHAFT, a body corporate organised under the laws of Germany, of 509 Leverkusen, Germany; do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to bandages containing water; more particularly, it relates to the manufacture of novel bandages based on stable polyurethane urea gels which contain water.

Bandages according to the present state of the art consist of woven or knitted materials which may also be combined with plastics sheets. Both natural and synthetic fibres may be used for the manufacture of the woven or knitted fabrics. Bandages which are required to have a cooling effect for the treatment of inflammatory swellings are usually dipped in water, but such swellings may also be treated with wet towels, handkerchiefs or other woven or knitted materials instead of bandages and the same method of treatment is also used for reducing high body temperatures, for example in infants and small children. In that case, wet towels or handkerchiefs are wrapped round the patient's calves. This procedure has numerous disadvantages, the main disadvantage being that textile materials of the above-mentioned type may only hold a very limited quantity of water and any excess would drop from the bandage and wet the surrounding areas.

It has now been found that the disadvantages of the bandages previously used may be overcome by using bandages made of materials based on aqueous polyurethane urea gels.

The materials used according to the present invention may consist of the gels alone or they may advantageously consist of combinations of the gels with any supporting layers on a basis of textile or non-textile products. These supporting layers may be bonded to the polyurethane on one or both sides.

The hydrogels and alcohol gels to be used according to the present invention, which are based on polyurethane polyureas, have in part been disclosed in German Offenlegungsschrift No. 2,347,299. They may be obtained by reacting isocyanate prepolymers of polyethers containing at least 40% by weight, of ethylene oxide units with diamines or higher polyamines or water as chain-lengthening agents in the presence of water and/or alcohols as dispersing agents, as well as perfumes and optionally other additives. The term "gel" is used herein in a general sense to describe the physical nature of the gel-like end product.

It has been found that bandages based on such gels, preferably polyurethane polyurea hydrogels, have numerous surprising advantages:

- (1) The water content in the gels may be greater than 90%, by weight, and may have any value below this figure. The water is absolutely firmly fixed in the polymer network even if the water content is 95%, by weight, and will not migrate from the gels.
- (2) The gels are mechanically strong and may be elastically stretched. They are found to have a high ultimate tensile strength.
- (3) Syneresis does not take place when the gels or bandages are left to stand. The water is immobilised so that the gel may be regarded as consisting of "solid water".
- (4) The gels or bandages containing the gels may be frozen at temperatures below the freezing point of water without destruction of or damage to the gel structure. Freezing is reversible and thawing and refreezing may be repeated indefinitely.
- (5) When the bandage is applied, a cooling effect takes place and water is slowly liberated from the gel or bandage. The water lost by this process may be restored to the polymer structure by leav-

ing the gel or bandage in water, that is to say the liberation and absorption of water are reversible.

(6) The gel products may easily be combined with the support materials. One particularly striking feature is the firm bond obtained between the gel and textile sheets.

(7) The gel masses may easily be shaped. They may be obtained as flat structures or they may be converted into any desired shapes in suitable moulds. This shaping is particularly useful if the dressings are required for the treatment of parts of the body which are difficult to bandage in the conventional way.

The present invention thus relates to the use, as dressings, of polyurethane urea gels containing water and/or alcohols and optionally also comprising supporting layers, intermediate layers and/or covering layers.

The present invention also relates to a process for the manufacture of bandages based on polyurethane urea gels containing water and/or alcohols, characterised in that isocyanate group-containing prepolymers which are obtained from polyethers containing at least 40%, by weight, of ethylene oxide units are mixed with water and/or polyamines as chain-lengthening agents in the presence of water and/or alcohols, and optionally also perfumes, pharmaceutical preparations and other additives, and the resulting mixture is applied to or between layers of support materials before the reaction is complete, this procedure optionally being accompanied by a shaping process.

Either water or alcohols or mixtures of both may be used for the preparation of the gels. The products of the process may therefore be divided into hydrogels and alcohol gels. The alcohols used may be either readily volatile monohydric alcohols, such as ethanol, isopropanol or butanol, or comparatively non-volatile polyhydric alcohols, such as ethylene glycol, diethylene glycol, glycerol or trimethylolpropane. In the preferred gels according to the present invention, at least 50%, by weight, of the dispersing agent consists of water.

Preparation of the gels may be carried out by various methods, for example all the components, i.e. the prepolymer, the dispersing agent, i.e. water and/or alcohol, perfumes, pharmaceutical preparations, chain-lengthening agents and any other additives may be added all at once, but they are preferably added stepwise. In that case, the perfumes, pharmaceutical preparations and any other additives, as well as cross-linking agents if used, e.g. polyamines, are dissolved in the dispersing agent. At the same time, an emulsion or solution of the prepolymer in the dispersing agent is prepared and the two

batches are then mixed in suitable stoichiometric proportions. The resulting mixture is poured into moulds or applied to textile or non-textile support materials. Whichever procedure is adopted, the reaction to form the gel which is used as bandage or part of a bandage takes place within a few seconds or minutes.

The end-product obtained may be a non-cellular solid or a foam, depending on the chain-lengthening agent used. Non-cellular gels are obtained when amines are used as chain-lengthening agents, but when water is used the products are foams due to the concomitant reaction of the isocyanate groups with water to produce gaseous carbon dioxide.

Vigorous mixing of the starting components facilitates the preparation of the gels and improves the quality thereof.

In the simplest case, mixing may be achieved in a zone of high turbulence produced by mechanical stirrers. Better results are obtained by using high speed mixing apparatus, such as impeller homogenizers or mixing chambers equipped with agitators of the type described in the literature or used in commercial polyurethane foaming machines. Vigorous mixing may also be achieved with the aid of mixing devices of polyurethane foaming machines in which the components are mixed by counterflow injection.

The gels may be poured or spread out to form endless webs of any desired thickness before they are cross-linked, and, if desired, these webs may be profiled.

It is particularly advantageous to apply the gels to support materials before they are cross-linked. These support materials may consist, for example, of woven or knitted fabrics, non-woven webs, foils or mesh fabrics based on natural and/or synthetic polymers, and these may also have a foam structure. Suitable foams for use as support materials are, in particular, the well known soft and semi-hard polyurethane foams. The thickness of the layers of gel may vary within wide limits and basically depends only on the requirements of the bandage. The gel layers generally have thicknesses of from 1 to 50 mm.

The prepolymers used for the preparation of the gels, consisting of polyethers containing at least 40%, by weight, of ethylene oxide units and of higher functional polyisocyanates still containing free isocyanate end groups, are prepared by reacting suitable polyethers with an excess quantity of polyisocyanate, that is to say using an isocyanate: hydroxyl ratio greater than 1:1, preferably from 1.5:1 to 20:1 most preferably from 2:1 to 10:1.

The optimum ratio for carrying out the process depends on the molecular weight, functionality and structure of the polyether. The isocyanate contents of the prepolymers should generally be from 2 to 20%, by

weight, preferably from 3.5 to 10%, by weight.

When amines are used as chain-lengthening agents, the prepolymers and amines are required to be used in substantially stoichiometric quantities for producing the bandage gels, but when carrying out the process on a technical scale it has been found that in order to obtain a suitable residence time of the reactants in the mixing assemblies it is advantageous to use an excess of amine component, i.e. an $\text{NH}_2:\text{NCO}$ ratio greater than 1:1, preferably from 1:1 to 1.2:1.

When water is used as chain-lengthening agent, the isocyanate groups and water may also be used in stoichiometrically equivalent proportions, but, if desired, especially for producing foam gels, a substantially larger quantity of water may be used. In that case, it is particularly advantageous also to use water as dispersing agent so that hydrogels in the form of foams are obtained. Water in that case fulfils a double function, first as reactant for the reaction with isocyanate groups and second as dispersing agent.

The quantity of water and/or alcohol present when the gels are being formed may vary within wide limits and is not critical. The weight of alcohol and/or water may be up to 98%, based on the total mass of gel. However, the properties of the gels obtained are strongly influenced by the proportion of polymer to dispersing agent. As a general rule, the gels obtained are progressively more stable and harder with increasing polymer content and softer and structurally less rigid and decreasing polymer content down to the lower limit of about 2%, by weight. The gels used according to the present invention preferably contain from 30 to 95%, by weight, of water and/or alcohol.

It is particularly surprising that the gel-based bandages according to the present invention are exceptionally stable. Even after prolonged storage, the gels undergo no visible phase separation which would be noticed, for example, by the material becoming cloudy. The dimensional stability is preserved even when the gels are stored at elevated temperatures and again no phase separation is observed. The dispersing agent is very firmly fixed in the gel, but may be liberated from it quite rapidly, according to its vapour pressure, and the body of the gel then gradually shrinks proportionately to its external dimensions. At this stage, perfumes and pharmaceutical preparations may also diffuse from the gel to be liberated to its surroundings, for example to the patient's skin. The liberation of dispersing agent causes additional cooling, especially if the dispersing agent is water. The liberation and reabsorption of dispersing agent from and into the gel is reversible. This means that when the gels have lost some of the dispersing agent, they may reabsorb

fresh dispersing agent and built it into the polymer structure when stored in pure dispersing agent.

Another surprising characteristic of the gels is that they may be frozen and thawed repeatedly any number of times without destruction of the structure thereof. This property is particularly advantageous when water is used as dispersing agent by virtue of its high thermal or cooling capacity. The bandages according to the present invention may therefore be stored indefinitely in refrigerators or cooling chests until they are required.

The starting materials required for the gels used according to the present invention include polyethers generally having a molecular weight of from 500 to 10,000, preferably from 2000 to 8000, which have at least two isocyanate reactive hydrogen atoms and contain at least 40%, by weight, of ethylene oxide units. Polyethers of this type may be prepared by reacting compounds containing reactive hydrogen atoms, e.g. polyhydric alcohols, with ethylene oxide and optionally also other alkylene oxides, such as propylene oxide, butylene oxide, styrene oxide, epichlorohydrin or mixtures of these alkylene oxides.

The following are examples of suitable polyhydric alcohols and phenols: ethylene glycol, diethylene glycol, polyethylene glycol, propane - 1,2 - diol, propane - 1,3 - diol, butane - 1,4 - diol, hexane - 1,6 - diol, decane - 1,10 - diol, butyne - 2 - diol - (1,4), glycerol, butane - 2,4 - diol, hexane - 1,3,6 - triol, trimethylolpropane, resorcinol, hydroquinone, 4,6 - di - tert - butyl pyrocatechol, 3 - hydroxy - 2 - naphthol, 6,7 - dihydroxy - 1 - naphthol, 2,5 - dihydroxy - 1 - naphthol, 2,2 - bis (*p* - hydroxyphenyl) - propane, bis - (*p* - hydroxyphenyl) - methane and α,α,ω - tris - (hydroxyphenyl) - alkanes, such as 1,1,2 - tris - (hydroxyphenyl) - ethane or 1,1,3 - tris - (hydroxyphenyl) - propane.

Other suitable polyethers include the 1,2 - alkylene oxide derivatives of ammonia or of aliphatic or aromatic monoamines or polyamines, such as methylamine, ethylene diamine, *N,N* - dimethylethylenediamine, tetra- or hexa-methylene diamine, diethylene triamine, ethanolamine, diethanolamine, oleyl-diethanolamine, methyl diethanolamine, triethanolamine, aminoethyl piperazine, *o*, *m*- and *p* - phenylene diamine, 2,4 - and 2,6 - diaminotoluene, 2,6 - diamino - *p* - xylene and multinuclear and condensed aromatic polyamines, such as 1,4 - naphthylene diamine, 1,5 - naphthylene diamine, benzidine, toluidine, 2,2 - dichloro - 4,4' - diamino-diphenylmethane, 1 - fluoroamine, 1,4 - anthradiamine, 9,10 - diaminophenanthrene and 4,4' - diaminoazobenzene. Resinous materials, such as phenols and resols, may also be used as starting molecules for the polyethers.

Ethylene oxide is included in the synthesis of all these polyethers.

The starting components used according to the present invention also include aliphatic, cycloaliphatic, araliphatic, aromatic and heterocyclic polyisocyanates of the type which have been described, for example, by W. Siefken in Justus Liebigs Annalen der Chemie, 562, pages 75 to 136. The following are examples: ethylene diisocyanate, tetramethylene - 1,4 - diisocyanate, hexamethylene - 1,6 - diisocyanate, dodecane - 1,12 - diisocyanate, cyclobutane - 1,3 - diisocyanate, cyclohexane - 1,3- and -1,4 - diisocyanate and mixtures of these isomers, 1 - isocyanato - 3,3,5 - trimethyl - 5 - isocyanato - methyl - cyclohexane (German Auslegeschrift No. 1,202,785), hexahydrotolylene - 2,4- and -2,6 - diisocyanate and mixtures of these isomers, hexahydrophenylene - 1,3- and/or -1,4 - diisocyanate, perhydrodiphenylmethane - 2,4'- and/or 4,4' - diisocyanate, phenylene - 1,3- and -1,4 - diisocyanate, tolylene - 2,4- and -2,6 - diisocyanate and mixtures of these isomers, diphenylmethane - 2,4' - and/or 4,4' - diisocyanate, naphthylene - 1,5 - diisocyanate, triphenylmethane - 4,4'4'' - triisocyanate, polyphenyl - polymethylene polyisocyanates which may be obtained by aniline - formaldehyde condensation followed by phosgenation and which have been described, for example, in British Patent Nos. 874,430 and 848,671, perchlorinated aryl polyisocyanates as described, e.g. in German Auslegeschrift No. 1,157,601, polyisocyanates containing carbodiimide groups as described in German Patent No. 1,092,007, the diisocyanates described in U.S. Patent No. 3,492,330, polyisocyanates having allophanate groups according to British Patent No. 994,890, Belgian Patent No. 761,626 and published Dutch Patent Application No. 7,102,524, polyisocyanates having isocyanurate groups as described, e.g. in German Patent Nos. 1,022,789; 1,222,067 and 1,027,394 and in German Offenlegungsschrift Nos. 1,929,034 and 2,004,048, polyisocyanates having urethane groups as described, e.g. in Belgian Patent No. 752,261 or in U.S. Patent No. 3,394,164, polyisocyanates having acylated urea groups according to German Patent No. 1,230,778, polyisocyanates containing biuret groups as described, e.g. in German Patent No. 1,101,394, British Patent No. 889,050 and in French Patent No. 7,017,514, polyisocyanates prepared by telomerisation reactions, e.g. as described in Belgian Patent No. 723,640, polyisocyanates containing ester groups as mentioned, e.g. in British Patent Nos. 956,474 and 1,072,956, in U.S. Patent No. 3,567,763 and in German Patent No. 1,231,688 and reaction products of the above-mentioned isocyanates with acetals according to German Patent No. 1,072,385.

The low molecular weight cross-linking or

chain-lengthening agents used may be aliphatic, cycloaliphatic, or aromatic diamines or higher polyamines, for example ethylene diamine, hexamethylene diamine, diethylene triamine, hydrazine, guanidine carbonate, N,N' - bis - (3 - aminopropyl) - ethylene diamine, N,N' - bis - (2 - aminopropyl) - ethylenediamine, N,N' - bis - (2 - aminoethyl) - ethylenediamine, 4,4' - dimethylamino - diphenylmethane, 4,4' - diamino - diphenyl - methane and 2,4 - and 2,6 - diaminotoluene.

Preparation of the prepolymers from polyethers and polyisocyanate is carried out by known methods, using NCO:OH ratios greater than 1:1.

A considerable quantity of both water-soluble and water-insoluble additives (i.e. additives which may be emulsified in water, if required with the addition of dispersing agents) may be added to the reaction mixtures for preparing the gels used in the manufacture of the bandages. Examples of suitable additives include: haemostatic agents, various pharmaceutical preparations, disinfectants, dyes, perfumes and cosmetic preparations for the skin, for example to regulate its moisture content. Other suitable additives include natural or other synthetic gel-formers, such as gelatin, carrageenates, alginates, polyvinyl alcohol and methyl cellulose. All these additives may be added to the gel compositions in quantities of up to 20 volumes percent.

Considerable quantities (up to 50 volumes percent) of various fillers may also be added in the preparation of the gels, for example silicates obtained from various silicas, aluminium oxides, tin oxides, antimony trioxide, titanium dioxide, graphite and graphitic carbon, carbon black, retort carbon, air-borne sand, pulverulent cements and various inorganic and organic dye pigments, such as iron oxide pigments, lead chromate, lead oxide and red lead. Short or long fibres of natural or synthetic materials, for example powdered cellulose, may also be used as fillers.

One advantage of using fillers is that it delays the liberation of the dispersing agent, i.e. of water and/or alcohol, as well as of any other additives, and therefore prolongs the time during which the bandage may be left on the patient before it requires to be renewed.

If desired, a gaseous component (generally air) may be added to the reaction mixture during gel formation. Gel bandages having a foam structure are thereby obtained, in which the unit weight (kg/m³) is substantially lower than that of the non-cellular material, depending on the quantity of gas incorporated.

One particular advantage of the process according to the present invention is that it may very easily be rendered continuous.

In a continuous process, the isocyanate prepolymers and, separately therefrom, the chain-

lengthening agent and dispersing agent are continuously introduced into a mixing zone at a temperature above the melting point and below the decomposition point of the isocyanate prepolymer, the chain-lengthening agent being introduced at such a rate that the isocyanate polyaddition reaction is not completed in the mixing zone. The polyurethane gel obtained in a still fluid and deformable state having a high water content or alcohol content is continuously removed from the mixing zone and, if required, is passed through a short reaction tube fitted with a shaped mouthpiece so that the resulting polyurethane gel is obtained as a completely shaped endless strand, band or sheet.

This gel may then be used as bandage on its own, but it is preferably combined with a support material by applying the vigorously mixed mass of gel continuously or intermittently to the textile or non-textile supports in conventional coating installations, for example by means of coating knives or by brush coating or casting.

The bandages obtained in this way may be sold open, but they are preferably sealed into waterproof foils which may be opened as required. This method of packaging may be carried out in conventional commercial automatic heat sealing machines.

The finished bandages may be used for various purposes in the medical and cosmetic fields, for example they may be used as bandages for the treatment of inflammatory swellings, as leg compresses for reducing the body temperature of infants, as compresses for localised or general lowering of the body temperature, particularly for carrying out operations on undercooled patients, as face masks and as ice packs.

Example 1

(a) Preparation of the prepolymer:

159 parts, by weight, of tolylene diisocyanate (80% 2,4- and 20% 2,6 - isomer) are heated to 80°C in a reaction vessel.

1200 parts, by weight, of a polyether having a hydroxyl number of 28 which has been obtained by the chemical addition of 60%, by weight, of ethylene oxide and 40%, by weight, of propylene oxide to glycerol are added dropwise with stirring over a period of 3 hours. The reaction mixture is then heated for one more hour at 80°C and left to cool to room temperature with stirring. The resulting prepolymer has an isocyanate content of 4.2%, by weight, and a viscosity of 5200 centipoises at 25°C.

(b) Manufacture of the bandage:

7 parts, by weight, of the prepolymer described under (a) are added to 59 parts, by weight, of water over a period of 3 seconds with mechanical stirring (rate of stirring 1165 revs/min). When the reaction mixture has

been stirred for 50 seconds, it is poured into a mould.

The interior of the mould measures 25×8×0.5 cm. A cotton fabric (muslin bandage, 34 g/m²) 8 cm in width is placed longitudinally on the base measuring 25×8 cm so that 10 cm of bandage overhangs the base at both ends.

60 seconds after the beginning of mixing, the reaction sets in with slight foaming (cream time). The gel time is 90 seconds. 10 minutes later, the foaming reaction is completed. The shaped product is removed from the mould after 5 minutes and sealed into an aluminium foil which has been coated with polyethylene on the side facing the bandage. The density of the gel product is 660 kg/m³.

The sealed bandage is stored at -20°C for 24 hours. The water in the bandage is then left to thaw and return to room temperature. The use properties of the bandage are not altered even when this process is repeated several times.

Example 2

The procedure is exactly the same as in Example 1(b), but a polyamide-based fabric having a mesh of 1 mm and a weight of 130 g/m² is used instead of the cotton fabric.

Example 3

The procedure is exactly the same as in Example 1(b), but a polyamide-based fabric (130 g/m²) is used instead of a cotton fabric and a polyethylene foil conforming to the dimensions of the base of the mould (25×8 cm) is placed on the reaction mixture at the beginning of the reaction so that the mixture is completely covered by the foil.

Example 4

The procedure is exactly the same as in Example 1(b), but instead of 59 parts, by weight, of water there is used an emulsion of 0.2 parts, by weight, of a dye of colour index No. 42 085, 3.5 parts, by weight, of a perfume oil (mixture of 60%, by weight, of isobornyl acetate and 40%, by weight, of the condensation product of 1 mol of nonyl phenol and 10 mol of ethylene oxide) and 55.3 parts, by weight, of water.

Example 5

The procedure is exactly the same as in Example 1(b), but the 59 parts, by weight, of water are replaced by an emulsion of 56 parts, by weight, of water and 3 parts, by weight, of an ointment for cuts and burns having the following composition: Phenolum liquefactum 1 g, Bismutum sabgallicum 5 g, Emplastrum Lithargyri 20 g, ointment base *ad* 100 g.

Example 6

The procedure is exactly as in Example

1(b), but using a suspension of 55 parts, by weight, of water and 4 parts, by weight, of pulverulent titanium dioxide instead of 59 parts, by weight, of water.

Example 7

The procedure is exactly the same as in Example 1(b), but using a mixture of 46 parts, by weight, of water and 13 parts, by weight, of propan - 2 - ol instead of 59 parts, by weight, of water.

Example 8

The procedure is exactly the same as in Example 1(b), but the reaction mixture used is a mixture of 9.5 parts, by weight, of the prepolymer described in Example 1(a) and 53.5 parts, by weight, of a solution consisting of 52 parts, by weight, of water and 1.5 parts, by weight, of the aluminium salt of acetic acid. The gel mass has a density of 630 kg/m³.

Example 9

The procedure is exactly the same as in Example 1(b), but the reaction mixture used is a mixture of 9.5 parts, by weight, of the prepolymer described in Example 1(a) and 53.5 parts, by weight, of a mixture of 52 parts, by weight, of water and 1.5 parts, by weight, of menthol. Measured from the beginning of the process of mixing the two reactants, the stirring time is 45 seconds, the cream time 60 seconds and the gel time 70 seconds. The density of the gel is 630 kg/m³.

Being aware of the Carcinogenic Substances Regulations, 1967, we make no claim herein to the use of the present invention in contravention of these Regulations.

WHAT WE CLAIM IS:—

1. A polyurethane urea gel containing water and/or at least one alcohol in a form suitable for use as a bandaging material.

2. A gel as claimed in claim 1 which con-

tains a supporting layer and/or an intermediate layer and/or a covering layer.

3. A gel as claimed in claim 1 or claim 2 which contains from 30 to 95%, by weight, of water and/or alcohol.

4. A gel as claimed in claim 1 substantially as herein described.

5. A gel as claimed in claim 1 substantially as herein described with reference to any one of the Examples.

6. A process for the preparation of a gel as claimed in claim 1 which comprises chain-lengthening at least one isocyanate prepolymer of a polyether containing at least 40%, by weight, of ethylene oxide units with water and/or at least one polyamine in the presence of water and/or at least one alcohol.

7. A process as claimed in claim 6 in which the reaction mixture is applied to a support layer and/or an intermediate layer and/or a covering layer before completion of the reaction.

8. A process as claimed in claim 7 in which the said application is accompanied by a shaping process.

9. A process as claimed in claim 6 substantially as herein described.

10. A process as claimed in claim 6 substantially as herein described with reference to any one of the Examples.

11. A gel when prepared by a process as claimed in any of claims 6 to 10.

12. A bandaging material comprising:
(a) a layer of a polyurethane urea gel containing water and/or alcohol; and, optionally,
(b) a supporting layer and/or an intermediate layer and/or a covering layer.

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